

### **DETAILED ACTION**

Applicant's response, filed 7 March 2011, has been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-57 are currently pending. Claims 26-44 and 54-57 are examined herein.

Claims 1-25 and 45-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 February 2009.

### **Priority**

The instant application claims priority to US 60/353,176, filed 4 February 2002 and to US 60/421,772, filed 29 October 2002. Priority to 60/353,176 is hereby denied, as the provisional application fails to disclose the instantly claimed invention. Specifically, the provisional application does not disclose profile models and the building of profiles according to genomics information that is identified for overlap and statistically analyzed to establish biological interactions. Priority to 60/421,772 is acknowledged. For purposes of applying prior art, the priority date accorded herein is 29 October 2002.

### **Response to Applicant's Arguments**

Applicant's traverse the denial of priority and state that US Provisional Application 60/353,176 discloses profile models and the building of profile models according to genomics

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information that is identified for overlap and statistically analyzed to establish biological interactions.

This is not persuasive. While it is acknowledged that the provisional application discloses that the invention makes use of structured database representations of information related to genes and that information is stored and accessed using an ontology, the provisional application fails to disclose the definition of a profile model based on criterion. Further, the provisional application fails to disclose any type of statistically significant profiles or the analysis used to generate the statistically significant profiles. As such, priority to the provisional application is denied.

### **Information Disclosure Statement**

The Information Disclosure Statement filed 9 March 2011 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

### **Petition**

The Petition filed under 37 CFR 1.47 filed 7 March 2011, which has been treated under 37 CFR 1.183, to waive the requirements of 37 CFR 1.131 has been granted. A separate communication has been mailed with regard to this matter.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-38, 40, 42-44 and 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by 2002/0194201 (Wilbanks et al.).

The instant claims are drawn to a computer system for evaluating user-supplied genomics data with a computer that has a structured database to store and access genomics information and the computer computes complex relationships among genes and/or gene products and the computer is configured to define a profile model, build a collection of profiles using the genomics information, identify overlaps of genomics data and statistically analyze profiles with genomics information.

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network. Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

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In regard to claim 27, Wilbanks et al. teach a priori data built in to the system (paragraph 0069).

In regard to claim 28, Wilbanks et al. teach profiles generated from graph structures (DWGs; paragraph 0086).

In regard to claim 29, Wilbanks et al. teach data query (paragraph 0013).

In regard to claim 30, Wilbanks et al. teach probability calculations (likelihood of success predictions; paragraph 0084, 0132, 0133).

In regard to claim 31, Wilbanks et al. teach databases with gene, gene product, and biological process information (paragraphs 0052 and 0087).

In regard to claim 32, Wilbanks et al. teach differential gene expression data (paragraph 0087).

In regard to claim 33, Wilbanks et al. teach disease data (paragraph 0112).

In regard to claim 34, Wilbanks et al. teach profile generation criterion using biological processes (entire document, 0135).

In regard to claim 35, Wilbanks et al. teach profile generation from nodes (paragraph 0089).

In regard to claim 36, Wilbanks et al. teach nodes that are genes, proteins, gene families etc... (paragraph 0089).

In regard to claim 37, Wilbanks et al. teach comparison to generate biological associations of the different profiles (paragraphs 0018, 0052, 0065, 0084, 0087).

In regard to claim 38, Wilbanks et al. teach data linkages (paragraph 0065).

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In regard to claim 40, Wilbanks et al. teach data annotation and associations that include cellular processes or disease processes (paragraphs 0087, 0088, 0112).

In regard to claim 42, Wilbanks et al. teach classifications of profiles from ontology information (paragraphs 0009, 0018, 0087).

In regard to claim 44, Wilbanks et al. teach profile models using different criterion wherein the a priori knowledge is represented by associated databases and the data can be merged/overlaid (paragraphs 0069, 0130)..

In regard to claim 54, Wilbanks et al. teach gene associations for disease using the relationship finder (paragraph 0112).

In regard to claim 55, Wilbanks et al. teach candidate development compounds (paragraph 0120).

In regard to claim 56, Wilbanks et al. teach disease-related pathways (paragraph 0112, 0120).

In regard to claim 57, Wilbanks et al. teach gene expression linked to markers which are linked to disease states (paragraphs, 0120, 0193-0195).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over 2002/0194201 (Wilbanks et al.), as applied to claims 26 and 40 above, in further view of Karp et al. (TIBTECH (1999) Vol. 17, pages 275-281; IDS reference).

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network. Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the

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establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

In regard to claim 40, Wilbanks et al. teach data annotation and associations that include cellular processes or disease processes (paragraphs 0087, 0088, 0112).

Wilbanks et al. do not specifically teach display of data using GUI, however Karp et al. teach integrated pathway-genome databases for drug discovery in which graphical user interface is used that includes a visualization tool for all data types (page 278). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the GUI of Karp et al. to display the ontology database profiles of Wilbanks et al., as GUI is a well-known interface for user-friendly operations. Both Karp et al. and Wilbanks et al. use genome databases to establish relational information.

**2.** Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over 2002/0194201 (Wilbanks et al.), as applied to claims 26 above, in further view of Qu et al. (Intelligent Systems in Biology (2002) March/April, pages 21-27; IDS reference; previously cited).

In regard to claim 26, Wilbanks et al. teach integrated biological/chemical databases formed by establishing entity-relationship models for each of the databases and identifying related entities in the relationship models (abstract). Wilbanks et al. further teach the identification of identical entities, thus teaching overlapping information (paragraph 0009). The plurality of databases represents an ontology that is integrated to create an ontology network.

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Wilbanks et al. teach a query of results stored as at least one new relationship in the entity-relationship model and the establishment of a confidence level that is assigned to at least one of the relationships (paragraph 0013). The biological databases include gene and protein sequence databases, genomic databases, gene prediction databases (paragraph 0052, 0132, 0133), among others. Wilbanks et al. teach cluster comparisons for data prediction and groupings (paragraph 0087).

Wilbanks et al. do not specifically teach the kind of statistical significance testing used that includes null hypothesis over probability. However, Qu et al. teach a system and method for integrating multidimensional data for relationship inference in genomics systems by implementing data from gene ontologies (page 22, column 3). Qu et al. also teach the calculation of relationship inference by statistical methods such as cluster analysis using hierarchical clustering employing the Pearson correlation coefficient to construct a relationship tree (page 24, column 3), showing that, in addition to the algorithms used by Wilbanks et al., various other statistical methodology may be employed to analyze relationship data for overlapping pathways, therefore making it prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the well-known statistical method of null hypothesis and probability distribution to analyze statistical significance of pathway overlap. One would have had a reasonable expectation of success in doing so because such databases were known and developed at the time of the invention and readily available for scientific use. Wilbanks et al. teach information gathering from a myriad of sources, including literature based findings, multiple databases and other findings (Figure 3).



**Declarations submitted under 37 CFR 1.131**

The Declarations filed on 7 March 2011 under 37 CFR 1.131 have been considered but are ineffective to overcome the prior art reference.

Firstly, Applicant states that “Applicant’s conceived of the invention and maintained diligence and/or reduced the invention to practice prior to May 13, 2002, the effective date of 2002/0194201 (Wilbanks et al.)”

Applicant will note that this is incorrect. The effective filing date under 102(e) of Wilbanks et al. is 5 June 2001 (earliest provisional Application filed as US 60/296,018, to which priority is claimed). Wilbanks et al. further claim priority to US Provisional Application 60/356,616, filed 13 February 2002. Both provisional applications were filed prior to the May 13, 2002 date. Therefore, the Declarations are not sufficient to overcome the effective filing dates of Wilbanks et al.

In addition, the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Wilbanks et al. reference to either a constructive reduction to practice or an actual reduction to practice. It is noted that the actual dates of acts relied upon to establish diligence must be provided in the Declaration (see MPEP 715.07(a)). No such dates have been provided herein.

Lastly, the declarations are insufficient to overcome the Wilbanks et al. reference because the exhibits relied upon (herein listed as Exhibits 1-4) are not specifically referred to in the Declarations in terms of what they are relied upon to show (see MPEP 715.07). Rather, the Declarations, themselves, merely point out what each exhibit is and not what each discloses in terms of the instantly claimed invention.

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As such, the prior art rejections of record are maintained and the Declarations are not accepted.

### **Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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June 30, 2011

/Lori A. Clow/

Primary Patent Examiner

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